

REMARKS

Claims 1-74 are pending in the application with claims 1, 2, 4-33 and 35-43 currently under examination. Claim 3 has been cancelled without prejudice. Claims 34 and 44-74 stand withdrawn from consideration as being directed to a non-elected invention. Claims 1, 16 and 32 have been amended. Support for the amendments can be found throughout the application as filed including, for example, at page 8, lines 23-28. Support for the amendment to step (a) of claim 1 can be found in step (b) of that claim. Accordingly, the amendments do not raise an issue of new matter and entry thereof is respectfully requested. Applicant has reviewed the rejections set forth in the pending Office Action, and respectfully traverse all grounds for the reasons that follow.

Rejections Under 35 U.S.C. § 101

Claims 1, 2, 4-33 and 35-43 stand rejected under 35 U.S.C. § 101 for being directed to non-statutory subject matter allegedly because they either lack a physical transformation outside a computer or lack a practical. The Office alleges that under the Interim Guidelines a method requires either a physical transformation or a concrete, tangible and useful result, or practical application. However, the claimed invention, directed to a method of predicting a behavior neither presents the identified correlative changes in a tangible form nor produces a concrete, tangible and useful result. The Office further concludes that Applicant neither argues that the claims do recite a physical transformation of matter or a concrete, tangible and useful result.

Applicants respectfully point out that they have previously made of record that the Federal case law is clear that a physical transformation is not required to satisfy the statutory criteria of § 101. See, for example, Applicant's Response dated June 15, 2004, at pages 13-14. Applicants further respectfully point out that the record also is clear that the claimed invention recites a practical application or a concrete, tangible and useful as set forth in *State Street Bank & Trust Co. v. Signature Financial Group*, 149 F.3d 1368 (1998), 525 U.S. 1093 (1999) (cert. denied). See, for example, Applicant's Response cited above at pages 13-14. Applicants respectfully request that the Office take note of these remarks of record. Further of note for the record, although the Office now refers to the Interim Guidelines published November 22, 2005, as the applicable authority over the M.P.E.P, Applicants respectfully point out that because the

entire rationale and express language of, for example, M.P.E.P. § 2106 (IV)(B)(1) is referenced in and can be found set forth in Annexes II-V of the Interim Guidelines, all arguments of record with respect to the M.P.E.P remain applicable and are maintained and reasserted herein.

Applicants maintain that all of the above remarks of record both address the Office's comments in the current Office Action and show that the requirements of § 101 have been adequately satisfied.

Although clear from the claims as written, claims 1, 16 and 32 to recite that an output of the identified correlative changes is provided to a user. The output of providing the identified correlative changes which predict a behavior of the biochemical system indicative of a changing condition is a concrete, tangible and useful result.

While not conceding that the Interim Guidelines are the applicable standard compared to the Federal case law precedent, the claimed result nevertheless satisfies the Office's Guidelines. The claimed result is concrete because it satisfies the Office's "useful result" criteria since it has a specific, substantial and credible utility. The utility of the claimed invention is specific to the subject matter claimed, and not general, because the claims recite that the claimed comparison of two or more data integration maps of a biochemical system predicts a behavior of the biochemical system. Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility, Nov. 22, 2005, section IV.B.2.b., *citing* M.P.E.P. § 2107 (*see also* Revised Interim Utility Guidelines Training Materials at page 5 (1999)). The utility is substantial because it has a real world use, namely, predictive capabilities of a behavior of a biochemical system of an organism's, such as for diagnostic or therapeutic purposes. *Id.* The utility also is credible because there is no reason for one skilled in the art to question the objective truth of the statement of utility and it is currently available for use. *Id.* Therefore, the claimed invention produces a useful result under the non-binding Interim Guidelines because it yields a specific, substantial and credible result.

Second, the claimed invention also satisfies the Office's "tangible result" criteria because it yields an output to a user for identified correlative changes that predict a behavior of the biochemical system. The Interim Guidelines correctly acknowledge that:

The tangible requirement does not necessarily mean that a claim must either be tied to a particular machine or apparatus or must operate to change articles or materials to a different state or thing.

Interim Guidelines, Nov. 22, 2005, section IV.B.2.b(2) (emphasis added); *see also In re Lundgren* cited in Applicants' previous response.

Therefore, consistent with the Office's current acknowledgement, there is no requirement for a claimed invention to be either tied to a particular machine or to transform a thing to a different state. Accordingly, any rejection based on this requirement is respectfully requested to be withdrawn.

Under this "tangible result" prong of the Office's guidelines, the requirement for a tangible result also must be differentiated from three judicial exceptions to patentability, which are: (1) laws of nature; (2) physical phenomena, and (3) abstract ideas. The guidelines further define the meaning of "tangible" to be opposite of "abstract."

With respect to the first two judicial exceptions above, the invention claims neither a law of nature or a physical phenomena *per se*. Rather, the claimed invention is directed to methods of predicting a behavior of a biochemical system. The methods include producing a comparison of two or more data integration maps of a biochemical system obtained under different conditions, identifying correlative changes in value sets between the integration maps and providing an output to a user of the correlative changes which is predictive of the biochemical system's behavior. There is no recitation in this claim of merely a law of nature or a physical phenomena. Accordingly, the claimed invention cannot be statutory unpatentable under these two judicial exception.

Further, there also is nothing in the claimed invention that constitutes a mere abstract idea. First, the claimed invention is more than just an idea because it claims a method of predicting a behavior of a biochemical system from data integration maps actually obtained under different conditions. The claimed method further identifies changes between the data integration maps and provides an output to a user which predicts a behavior of the biochemical system indicative of the changing condition. Hence, the ability to predict an organism's biochemical behavior is more than an idea. Rather, it is an actual outcome.

Second, the claimed invention also is not abstract. The term “abstract” is defined as:

[c]onsidered apart from any application to a particular object or specific instance insufficiently factual having no reference to a thing or things -- opposed to concrete. . . . Expressing a property, quality, attribute, or relation viewed apart from the other characteristics inhering in or constituting an object.

Webster's Third New International Dictionary, Unabridged. Merriam-Webster, 2002.

<http://unabridged.merriam-webster.com> (21 Aug. 2006) (emphasis added).

Applicants maintain that the claimed invention is sufficiently factual because it recites producing a comparison of two or more data integration maps of a biochemical system obtained under different conditions, identifying and providing an output to a user of identified changes between the data integration maps where the identified changes predict a behavior of the biochemical system. Further, the claimed invention is not claimed apart from, or without reference to a thing or to characteristics of an object because it specifically recites that the value sets are comprised from data elements obtained from a biochemical system under different sets of conditions. Accordingly, the invention is concrete and not abstract because it is sufficiently factual and does not recite purely theoretical ideas detached from a particular object. Therefore, the claimed invention also produces a tangible result under the non-binding Interim Guidelines because it does not claim a law of nature, a physical phenomena or merely abstract idea apart from any application to a particular object.

Finally, the claimed invention also satisfies the Office’s “concrete result” criteria. The Interim Guidelines define this prong as being the opposite of “concrete” which is “unrepeatable or unpredictable.” Interim Guidelines, Nov. 22, 2005, section IV.B.2.b(3). Applicants respectfully point out that the invention claims producing an output to a user of identified changes between two or more data integration maps which predicts a behavior of the biochemical system. Further, the application provides detailed teachings and guidance throughout for how to make and use the invention by obtaining the two or more data integration maps from data elements obtained under different conditions, comparing and identifying the changes in value sets, and producing the output to a user, whereby the output yields a prediction of the biochemical system’s behavior. Therefore, the claimed invention further produces a

concrete result under the non-binding Interim Guidelines because it yields a result that is predicts a property of a biochemical system.

In light of the above, Applicants maintain that claims 1, 2, 4-33 and 35-43 are directed to statutory patentable subject matter which has a practical application under the Federal case law precedent. Applicants further maintain that claims 1, 2, 4-33 and 35-43 also satisfy the Offices non-binding guidelines for statutory patentable subject matter for computer related inventions. Accordingly, withdrawal of this ground of rejection is respectfully requested.

Rejections Under 35 U.S.C. § 102

Claims 1, 2, 4-33 and 35-43 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Rine et al. The Office alleges that Applicants' claimed data integration maps fail to recite Applicants' argued distinction. In particular, the Office fails to give patentable weight to Applicants' showing that Rine et al. compare values obtained from microarray profiles without producing an integration map of different types of results or data elements into a value set as claimed allegedly because "the instant claims do not recite an 'integration of different types of results' or 'data elements integrated into a value set' but rather data integration maps." Office Action at page 8, second paragraph.

Applicants respectfully disagree. The application also teaches that a value set means two or more types of data elements that characterize a component of biochemical system (see, for example, page 18, lines 27-29). The claimed invention expressly recites that the claimed data integration maps include value sets containing two or more different types of data elements because a comparison is made where correlative changes are identified in at least two value sets containing different types of data elements. Although believed to be clear in the claims as written, Applicants have reiterated in step (a) of claim 1 this element recited in step (b) which explicitly states that the data integration maps are comprised of value sets containing two or more different types of data elements. Accordingly, Applicants' expressly claim data integration maps containing value sets having two or more different types of data elements.

Rine et al. fail to describe this element because Rine et al. describe a stimulated physical matrix. The stimulated physical matrix of Rine et al. described at, for example, column 2, lines

4-15, is directed to a physical matrix of living things, or responders, that are then assayed. The results are related back to the responders and not to each other.

For example, column 2, lines 4-15, states:

Generating an output signal matrix database according to the invention involves: (I) constructing a stimulated physical matrix; (ii) detecting a physical signal at each unit of the physical matrix; (iii) transducing each physical signal to generate a corresponding electrical output signal; (iv) storing each output signal in an output signal matrix data structure associating each output signal with the X and Y coordinates of the corresponding physical matrix unit and the stimulus; and (v) repeating steps (I)-(iv) to iteratively store output signal matrix data structures for a plurality of stimuli to form an output signal matrix database indexing output signal matrix data structures by stimuli.

Id. (emphasis added).

As indicated by the underlined passage, the signal obtained from the responders is described to be correlated back to its X-Y location in the physical matrix. The above passage is silent as to any association of data elements with each other to form a value set or as to any integration into a map that describes the interactions, interrelations and interdependencies of the components of a biochemical system. Therefore, neither the Office nor the cited passage in Rine et al. describe an integration map containing values sets with different types of data as is claimed by the invention.

Therefore, Rine et al. produce a database of the same type of data and compare that same type of data elements obtained under different conditions. Rine et al. fail to describe two or more different types of data elements contained in a value set and, similarly, cannot describe an integration map having such two or more value sets containing different types of data elements. Absent any description in Rine et al. of generating and combining different types of data into a value set as Applicants' claim, Rine et al. cannot anticipate the invention as claimed.

Applicants further respectfully disagree with the Office's repetition of purported descriptions in Rine et al. that allegedly anticipate the claimed invention at, for example, pages 9-11 of the Office Action. For example, the apparent analogy used by the Office between a data integration map, physical interaction map and interaction map is unfounded. As Applicants have previously set forth of record, a data integration map and physical interaction map differ. The

term “integration map” is a construction of the Office and is irrelevant to the claimed invention. Applicants reassert by incorporation their remarks of record. They amply distinguish the alleged descriptions in Rine et al. that the Office maintains in the current Office Action.

Accordingly, the invention expressly claims data integration maps including value sets containing two or more different types of data elements. Rine et al. fails to describe this element because Rine et al. simply produces a database having the same type of data. Therefore, Rine et al. fails to teach each and every element of the claimed invention and cannot anticipate the invention as claimed. Withdrawal of this ground of rejection is respectfully requested.

CONCLUSION

In light of the Remarks herein, Applicant submits that the claims are in condition for allowance and respectfully request a notice to this effect. Should the Examiner have any questions, she is invited to call the undersigned attorney.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502624 and please credit any excess fees to such deposit account.

Respectfully submitted,

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